II

106TH CONGRESS
2D SESSION

S. 3082

To amend title XVIII of the Social Security Act to improve the manner in which new medical technologies are made available to Medicare beneficiaries under the Medicare Program, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 20, 2000

Mr. HATCH introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend title XVIII of the Social Security Act to improve the manner in which new medical technologies are made available to Medicare beneficiaries under the Medicare Program, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Medicare Access to Technology Act of 2000''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. ANNUAL REPORTS ON NATIONAL COVERAGE DETERMINATIONS.

(a) ANNUAL REPORTS.—Not later than December 1 of each year, beginning in 2001, the Secretary of Health and Human Services shall submit to Congress a report that sets forth a detailed compilation of the actual time periods that were necessary to complete and fully implement any national coverage determinations that were made in the previous fiscal year for items, services, or medical devices not previously covered as a benefit under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), including, with respect to each new item, service, or medical device, a statement of the time taken by the Secretary to make the necessary coverage, coding, and payment determinations, including the time taken to complete each significant step in the process of making such determinations.

(b) PUBLICATION OF REPORTS ON THE INTERNET.—The Secretary of Health and Human Services shall pub-

lish each report submitted under subsection (a) on the medicare Internet site of the Department of Health and Human Services.

SEC. 3. IMPROVEMENTS TO THE MEDICARE ADVISORY COMMITTEE PROCESS.

Section 1114 of the Social Security Act (42 U.S.C. 1314) is amended by adding at the end the following new subsection:

''(i)(1) Any advisory committee appointed under subsection (f) to advise the Secretary on matters relating to the interpretation, application, or implementation of section 1862(a)(1) shall assure the full participation of a nonvoting member in the deliberations of the advisory committee, and shall provide such nonvoting member access to all information and data made available to voting members of the advisory committee, other than information that—

''(A) is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section (relating to trade secrets); and

''(B) the Secretary determines would present a conflict of interest relating to such nonvoting member.

''(2) If an advisory committee described in paragraph (1) organizes into panels of experts according to types of items or services considered by the advisory committee, any such panel of experts may report any recommendation with respect to such items or services directly to the Secretary without the prior approval of the advisory committee or an executive committee thereof.''.

SEC. 4. INCLUSION ON MEDPAC OF AN INDIVIDUAL WITH EXPERTISE IN NEW MEDICAL DEVICES.

(a) IN GENERAL.—Section 1805(c)(2)(B) of the Social Security Act (42 U.S.C. 1395b–6(c)(2)(B)) is amended by inserting ''individuals with national recognition for their expertise in the development for market of new medical items, services, and devices,'' after ''other health professionals,''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) applies with respect to members appointed to the Medicare Payment Advisory Commission on or after the date of the enactment of this Act.

SEC. 5. ANNUAL ADJUSTMENTS TO MEDICARE PAYMENT SYSTEMS FOR CHANGES IN TECHNOLOGY AND MEDICAL PRACTICE.

(a) IN GENERAL.—Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by inserting after section 1888 the following new section:

"ANNUAL ADJUSTMENTS TO MEDICARE PAYMENT SYSTEMS FOR CHANGES IN TECHNOLOGY AND MEDICAL PRACTICE

"SEC. 1889. (a) IN GENERAL.—

"(1) ASC, MFS, AND INPATIENT PPS.—Notwithstanding any other provision of this title, the Secretary shall adjust the appropriate elements of the payment systems established under sections 1833(i)(2)(A), 1848, and 1886(d) (including relative payment weights, relative value units, weighting factors, diagnosis-related group classifications, and assignments to diagnosis-related groups) at least annually to ensure that payments under such systems appropriately reflect changes in medical technology and medical practice affecting the items and services for which payment may be made under such systems.

"(2) OP PPS.—For a provision requiring adjustments to the elements of the outpatient prospective payment system at least annually, see section 1833(t)(9)(A).

"(b) RULES FOR DETERMINING ADJUSTMENTS.—Except as provided in subsection (c), the provisions of section 1833(i)(2)(A), section 1848(c)(2)(B), and section 1886(d)(4)(C) shall apply to the annual adjustments re-

quired by this section in the same manner and to the same extent as they apply to the periodic adjustments of relative payment weights, relative value units, weighting factors, diagnosis-related group classifications, and assignments to diagnosis-related groups, respectively, that are authorized or required by such sections.

''(c) USE OF INTERNAL DATA COLLECTED BY THE SECRETARY.—

''(1) IN GENERAL.—In determining the adjustments required by this section and section 1833(t)(9)(A), the Secretary may not—

''(A) decline to make an adjustment that is based on data collected by the Secretary in the administration of the program established under this title if the data reflect a representative sample of cases that is statistically valid; and

''(B) establish a uniform period of time (such as one year) from which such data must be drawn.

''(2) DEADLINE FOR SUPPLYING INTERNAL DATA.—The Secretary shall establish a reasonable deadline for the submission of data collected by the Secretary to be used in making the adjustments required by this section or section 1833(t)(9)(A). In

no event may the deadline established under this paragraph be more than seven months before the first day of the provider payment update period for which the adjustment or adjustments to which the data relate would be effective.

''(d) USE OF EXTERNAL DATA.—

''(1) IN GENERAL.—Subject to paragraph (2), in determining the adjustments required by this section and section 1833(t)(9)(A), the Secretary shall utilize data other than data collected by the Secretary in the administration of the program established under this title if—

''(A) data collected by the Secretary in the administration of such program are not available at the time such adjustments are being determined; and

''(B) such other data are reliable and verifiable.

''(2) EXTERNAL DATA FACILITATING THE USE OF INTERNAL DATA.—

''(A) IN GENERAL.—In determining the adjustments required by this section and section 1833(t)(9)(A), the Secretary may not—

''(i) decline to use data other than data collected by the Secretary if such other data—

''(I) enable the Secretary to identify or refine data collected by the Secretary for use in making such an adjustment; and

''(II) are based on a representative sample of cases that is statistically valid; or

''(ii) establish a uniform period of time (such as one year) from which such data must be drawn.

''(B) SPECIAL RULE.—

''(i) WAIVER OF REQUIREMENT FOR INDIVIDUAL AUTHORIZATION FOR DISCLOSURE OF PROTECTED HEALTH INFORMATION.—Notwithstanding any other provision of law, individual authorization is not required for disclosure of protected health information to—

''(I) a government agency or private payer; or

''(II) a private entity for the purpose of disclosure to such an agency or payer,

for inclusion in data systems of the agency or payer for use in the formulation of coverage, coding, and payment policies of the agency or payer.

''(ii) CONSTRUCTION.—Nothing in clause (i) shall be construed as authorizing the disclosure or use of such information by such an agency, payer, or entity for any other purpose.

''(3) ALTERNATIVE SOURCES OF DATA.—In determining the adjustments required by this section and section 1833(t)(9)(A), the Secretary shall use data, that otherwise meet the requirements of this subsection, collected by (or on behalf of)—

''(A) private payers;

''(B) manufacturers of medical technologies;

''(C) suppliers;

''(D) groups representing physicians and other health care professionals;

''(E) groups representing providers;

''(F) clinical trials; and

"(G) such other sources as the Secretary determines to be appropriate.

"(4) CLARIFICATION.—Nothing in this title shall be construed as—

"(A) requiring the Secretary to identify all claims submitted under a payment system established under section 1833(i)(2)(A), section 1833(t), section 1848, or section 1886(d) involving the use of a medical technology before the Secretary may make the adjustments under this section (or under section 1833(i)(2)(A), section 1833(t), section 1848, or section 1886(d)) with respect to such technology; or

"(B) authorizing the Secretary to defer action on such an adjustment until all such claims are identifiable.

"(5) DEADLINE FOR SUPPLYING EXTERNAL DATA.—The Secretary shall establish a reasonable deadline for the submission of data other than data collected by the Secretary to be used in making the adjustments required by this section or section 1833(t)(9)(A). In no event may the deadline established under this paragraph be more than 9 months before the first day of the provider payment update

period for which the adjustment or adjustments to which the data relate would be effective.

''(e) TIMING OF ADJUSTMENTS.—

''(1) IN GENERAL.—The annual adjustments required by this section shall—

''(A) apply to provider payment update periods beginning on or after October 1, 2001; and

''(B) be described in the proposed and final rules published by the Secretary with respect to changes to a payment system established under section 1833(i)(2)(A), 1848, or 1886(d) for the provider payment update period to which they relate, together with a description of the data on which such adjustments are based.

''(2) DEFINITION.—For purposes of this section, the term 'provider payment update period' means—

''(A) in the case of the payment system established under section 1833(i)(2)(A) or section 1848, a calendar year; and

''(B) in the case of the payment system established under section 1886(d), a fiscal year beginning on October 1.''.

(b) CONFORMING AMENDMENTS.—

(1) AMBULATORY SURGICAL CENTERS.—Section 1833(i)(2)(A) of the Social Security Act (42 U.S.C. 1395l(i)(2)(A)) is amended by striking ''Each'' in the second sentence thereof and inserting ''Subject to section 1889, each''.

(2) PHYSICIAN PAYMENT.—Section 1848(c)(2)(B)(i) of such Act (42 U.S.C. 1395w–4(c)(2)(B)(i)) is amended by striking ''The'' and inserting ''Subject to section 1889, the''.

(3) INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM.—Section 1886(d)(4)(C)(i) of such Act (42 U.S.C. 1395ww(d)(4)(C)(i)) is amended by striking ''The'' and inserting ''Subject to section 1889, the''.

SEC. 6. ANNUAL REPORTS ON ELIMINATION OF BARRIERS TO USE OF NEW MEDICAL DEVICES IN HOSPITAL OUTPATIENT SETTINGS.

(a) REPORT BY SECRETARY ON ACCESS TO DEVICES.—Section 1833(t)(13) of the Social Security Act (42 U.S.C. 1395l(t)(13)) is amended by adding at the end the following new subparagraph:

''(B) REPORT ON ACCESS TO DEVICES.—Not later than December 1 of each year beginning with 2001, the Secretary shall submit to

Congress a report on access of individuals furnished covered OPD services (as defined in paragraph (1)(B)) to medical devices in conjunction with such services. Such report shall include an analysis of the impact of paragraph (6)(A) in making new devices available in hospital outpatient departments, the extent to which barriers to such availability have been overcome by reason of such paragraph, the impact of including or excluding a device under the payment system established by this subsection on beneficiary access to such device, and a description of efforts by the Secretary to increase the use and availability of such devices in such departments. For purposes of this subparagraph, the term 'device' means any item that is treated as a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act.''.

(b) MEDPAC REPORT ON NEW DEVICES.—Section 1805(b)(2)(C) of the Social Security Act (42 U.S.C. 1395b–6(b)(2)(C)) is amended by adding at the end the following: ''In conducting such review, the Commission shall monitor medicare beneficiary access to medical devices for which payment is made under section 1833(t) in hospital outpatient departments, shall assess the impact

of paragraph (6)(A) of such section in making new devices available in such departments, the extent to which barriers to such availability have been overcome by reason of such paragraph, and the impact of including or excluding a device under the payment system established by section 1833(t) on beneficiary access to such device, and shall make any recommendations the Commission determines would increase availability of such devices to individuals entitled to benefits under this title. For purposes of this subparagraph, the term 'device' means any item that is treated as a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act.''.

SEC. 7. CLARIFICATION OF STANDARD FOR COVERAGE OF DRUGS AND BIOLOGICALS.

(a) IN GENERAL.—Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)) is amended by adding at the end the following: ''A drug or biological may not be excluded from coverage under this title by reason of paragraph (1)(A) if the drug or biological has been approved by the Food and Drug Administration and is prescribed for a use that has been approved by the Food and Drug Administration or that is supported by one or more citations that are included (or approved for inclusion) in one or more of the compendia referred to in section 1861(t)(2)(B)(ii)(I).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to coverage determinations made on or after the date of enactment of this Act.

SEC. 8. PROCESS FOR MAKING AND IMPLEMENTING HCPCS CODING MODIFICATIONS.

(a) IN GENERAL.—Notwithstanding any other provision of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), the Secretary of Health and Human Services shall—

(1) not later than 30 days after the receipt of a written request of a product sponsor, assign a temporary code to a drug or device reviewed by the Food and Drug Administration;

(2) accept recommendations for HCPCS level II code modifications from the public throughout the year;

(3) cause determinations on such recommendations to be made within 30 days after receipt of the recommendation; and

(4) incorporate modifications to HCPCS level II codes that are approved during the 3 months preceding the last month of a calendar quarter into the payment systems established under such title (including the medicare fee schedule data base) not

later than the first day of the following calendar quarter.

(b) ELIMINATION OF REQUIREMENT FOR MARKETING EXPERIENCE.—Notwithstanding any other provision of title XVIII of the Social Security Act, the Secretary of Health and Human Services may not require a minimum period of marketing experience with respect to a drug or device as a condition of consideration or approval of a recommendation for an HCPCS level II modification for such drug or device.

(c) DEFINITION.—For purposes of this section, the term ''HCPCS level II code modification'' means any change to the alphanumeric codes for items not included in level I or level III of the Health Care Financing Administration Common Procedure Coding System (HCPCS).

(d) REPORT.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report on the feasibility and desirability of opening meetings of the Alpha-Numeric Editorial Panel of the Department of Health and Human Services to the public. If the Secretary determines that opening such meetings to the public is not feasible or desirable, the Secretary shall include in the report a detailed explanation of the reasons for such determination.

(e) EFFECTIVE DATE.—The provisions of this section take effect on January 1, 2001.

SEC. 9. RETENTION OF HCPCS LEVEL III CODES.

(a) IN GENERAL.—The Secretary of Health and Human Services shall maintain and continue the use of level III codes of the HCPCS coding system (as such system was in effect on June 1, 1999), and shall make such codes available to the public.

(b) DEFINITION.—For purposes of this section, the term ''HCPCS Level III codes'' means the alphanumeric codes for local use under the Health Care Financing Administration Common Procedure Coding System (HCPCS).

SEC. 10. PROCESS FOR MAKING AND IMPLEMENTING ICD–9–CM CODING MODIFICATIONS.

(a) IN GENERAL.—Notwithstanding any other provision of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), with respect to payments for inpatient hospital services under section 1886 of such Act (42 U.S.C. 1395ww), the Secretary of Health and Human Services shall—

(1) not later than 30 days after the receipt of a written request of a product sponsor, assign a temporary code to a drug or device reviewed by the Food and Drug Administration;

(2) accept recommendations for ICD–9–CM code modifications from the public throughout the year;

(3) cause determinations on such recommendations to be made within 30 days after receipt of the recommendation; and

(4) incorporate modifications to ICD–9–CM codes that are approved during the 3 months preceding the last month of a calendar quarter into the payment systems established under such title (including the medicare fee schedule data base) not later than the first day of the following calendar quarter.

(b) ELIMINATION OF REQUIREMENT FOR MARKETING EXPERIENCE.—Notwithstanding any other provision of title XVIII of the Social Security Act, the Secretary of Health and Human Services may not require a minimum period of marketing experience with respect to an item, service, or device for which payment is made under such section 1886 as a condition of consideration or approval of a recommendation for an ICD–9–CM modification for such item, service, or device.

(c) DEFINITION.—For purposes of this section, the term ''ICD–9–CM code modification'' means any change to the alphanumeric codes of the International Classifica-

tion of Diseases, 9th Revision, Clinical Modification, applied under such section 1886.

(d) MEDPAC REPORT.—Not later than January 1, 2001, the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6) shall submit to Congress a report on—

(1) the procedures used by the Health Care Financing Administration to makes changes to the classification system, diagnosis-related groups, and weighting factors established under paragraph (4) of section 1886(d) of such Act (42 U.S.C. 1395ww(d)) to incorporate new technologies and respond to changes in technology;

(2) whether such procedures ensure that the payments made under the prospective payment system established under such section are appropriate and timely for new technologies and provide appropriate and timely recognition of changes in the technology; and

(3) recommendations for such legislation and administrative actions as the Commission considers appropriate to promote the appropriate and timely incorporation of new technologies and the recognition of changes in technology under such system.

SEC. 11. ESTABLISHMENT OF PROCEDURES FOR MEDICARE CODING AND PAYMENT DETERMINATIONS FOR NEW CLINICAL DIAGNOSTIC LABORATORY TESTS AND OTHER ITEMS ON A FEE SCHEDULE.

(a) IN GENERAL.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall establish procedures for coding and payment determinations for the following categories of items and services under part B of the title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.): new clinical diagnostic laboratory tests and durable medical equipment. Such procedures (which may vary for the 2 categories of items and services referred to in the preceding sentence) shall provide for the following:

(1) Such procedures shall be clearly understandable and follow a predictable format. Any hearings or meetings with respect to the determinations shall be open to the public and provide for public participation.

(2) Under the procedures, the Secretary shall identify the rules and assumptions to be applied in considering the coding or payment determination, and shall provide the sources and types of data to be used in making such determination.

(3) Under the procedures, the Secretary shall provide a clear statement of the basis for the determination.

(4) Under the procedures, the Secretary shall make available to the public the data (other than proprietary data) considered in making the determination.

(5) Under the procedures, the Secretary shall consider and implement coding modifications under procedures similar to those for HCPCS level II and ICD–9–CM procedure and related codes.

(6) Under the procedures, the Secretary shall provide for consistent instructions to carriers to carry out their functions in setting prices for new technologies that—

(A) are designed to establish fair and appropriate payment levels reflecting market conditions for such items and services; and

(B) in the case of clinical diagnostic laboratory tests for which payment is made on a fee schedule basis under title XVIII of the Social Security Act, comply with the requirements of section 1833(h)(8) of such Act (42 U.S.C. 1395l(h)(8)).

(7) Under the procedures, the Secretary shall provide a mechanism under which an interested party may request a timely review of the adequacy of the existing fee for a particular item or service, and upon receipt of such a request that such timely review is carried out.

(8) Under the procedures, the Secretary shall provide for a mechanism under which an interested party may request administrative review of an adverse coding or payment policy determination, and shall provide for such review and, if necessary, revision of the determination.

(b) ESTABLISHING PAYMENT RATES FOR NEW LAB TESTS.—Section 1833(h) of the Social Security Act (42 U.S.C. 1395l(h)) is amended by adding at the end the following:

''(8)(A) Notwithstanding paragraphs (1), (2), and (4), in the case of a clinical diagnostic laboratory test with respect to which a code is first assigned under the Health Care Financing Administration Common Procedure Coding System (hereinafter referred to as 'HCPCS') on or after January 1, 2001, the Secretary shall provide for the establishment of payment rates in accordance with subparagraph (B) or (C).

''(B) In the case of a clinical diagnostic laboratory test described in subparagraph (A) with respect to which the Secretary proposes to base payment on the fee schedule amounts determined under paragraph (1) and the national limitation amount determined under paragraph (4) for one or more similar clinical diagnostic laboratory tests, the Secretary shall—

''(i) cause to have published in the Federal Register not later than July 1 of each calendar year (beginning with calendar year 2001) the Secretary's proposal with respect to the appropriate fee schedule amounts and national limitation amount for such test for the following calendar year; and

''(ii) provide an opportunity for the public to comment on such proposal.

''(C)(i) In the case of a clinical diagnostic laboratory test described in subparagraph (A) with respect to which payment is not determined in accordance with subparagraph (B)—

''(I) payment under this subsection shall be made on the basis of the prevailing charge level for the test for a locality or area (determined without regard to the percentage limitation or the base year referred to in paragraph (2)(A)); and

''(II) the limitation amounts referred to in subsection (a)(1)(D)(i), subsection (a)(2)(D)(i), and paragraph (4)(B) shall not apply,

until the beginning of the third full calendar year that begins on or after the date on which an HCPCS code is first assigned with respect to such test, or, if later, the beginning of the first calendar year that begins on or after the date on which the Secretary determines that there are sufficient claims data to establish a limitation amount under paragraph (4)(B).

''(ii) Notwithstanding paragraph (2)(A), the Secretary shall—

''(I) set the fee schedules under paragraph (1) for a clinical diagnostic laboratory test described in clause (i) for any calendar year beginning after the base year at 100 percent of the prevailing charge level for such test for the applicable region, State, or area for the base year, adjusted annually (to become effective on January 1 of each year) by the percentage increase or decrease in the Consumer Price Index for All Urban Consumers (United States city average), and subject to such other adjustments as the Secretary determines are justified by technological changes; and

"(II) determine the limitation amount referred to in subsection (a)(1)(D)(i), subsection (a)(2)(D)(i), and paragraph (4)(B) for such test based on the fee schedules set under subclause (I).

"(iii) For purposes of clause (ii), the term 'base year' means, with respect to a clinical diagnostic laboratory test, the last full calendar year during which payment for such test was determined in accordance with clause (i).".

(c) PROHIBITION.—The Secretary may not assign a code for a new clinical diagnostic laboratory test that differs from the code recommended by the American Medical Association Common Procedure Terminology Editorial Panel and results in lower payment than would be made if the Secretary accepted such recommendation solely on the basis that the test is a test that may be performed by a laboratory with a certificate of waiver under section 353(d)(2) of the Public Health Service Act (42 U.S.C. 263a(d)(2)).

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